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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/820,099	03/27/2001	Jan G.J. van de Winkel	MXI-170	2545

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EXAMINER	
BLANCHARD, DAVID J	

ART UNIT	PAPER NUMBER
1643	

DATE MAILED: 01/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/820,099	VAN DE WINKEL, JAN G.J.	
	Examiner	Art Unit	
	David J. Blanchard	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 September 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 6-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 6-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *8/3/01; 1/22/02*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 2-5 and 13-24 are cancelled.

2. Claims 1 and 6-12 are pending and under examination.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. This Office Action contains New Grounds of Rejections.

Withdrawn Rejections

5. The rejection of claims 1 and 6-12 under 35 U.S.C 103(a) as being unpatentable over Shen et al (WO 98/23646, published 6/98, Ids reference A22 filed 8/3/01) as evidenced by Monteiro et al (Journal of Experimental Medicine 171:597-613, 1990) and the specification is withdrawn in view of the decision rendered by the Board of Patent Appeals and Interferences mailed 9/28/05.

Claim Rejections - 35 USC § 102

6. Claims 1, 6, 8 and 11-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Mannhalter et al (U.S. Patent 5,808,000, issued 9/15/1998).

The claims are interpreted as being drawn to a method for eliminating a target cell or antigen from the circulatory system of a subject comprising administering to the subject a complex comprising monomeric IgA that binds to FcαRI, linked to a second portion (i.e., antigen-binding domain) that binds a target cell or antigen wherein the antigen is selected from a bacteria, a virus and a fungus and wherein monomeric IgA

(i.e., "the complex") is administered by intravenous injection. For this rejection, the complex comprising monomeric IgA that binds to FcαRI, linked to a second portion which specifically binds the target cell or antigen is interpreted read on monomeric IgA, which comprises an Fc region that binds FcαRI and the Fc region is linked to an antigen-binding fragment (i.e., Fab), which specifically binds a target cell or antigen.

Mannhalter et al teach a method of treating inflammations, infections and allergies, including bacterial and viral infections in a subject comprising administering monomeric IgA by intravenous injection (see entire document, particularly columns 6-7 and 1). Therefore, the administration of monomeric IgA taught by Mannhalter et al reads on the claims because the Fc region of monomeric IgA binds FcαRI and the Fc region is linked to an antigen-binding fragment (i.e., Fab fragment), which specifically binds a target cell or antigen (i.e., bacterial or viral).

Thus, Mannhalter et al anticipate the claims.

7. Claims 1, 6 and 8-11 are rejected under 35 U.S.C. 102(b) as being anticipated by van Spriel et al (Journal of Infectious Diseases, 179(3):661-669, first publicly available date of 3/3/1999) as evidenced by Van Egmond et al (Nature Medicine, 6(6):68-685, June 2000, IDS reference F2 filed 1/22/02).

The claims are interpreted as being drawn to a method for eliminating a target cell or antigen from the circulatory system of a subject comprising administering to the subject a complex comprising a portion of monomeric IgA (i.e., F(ab) fragment) that binds to FcαRI, linked to a second portion (i.e., antigen-binding domain) that binds a

target cell or antigen wherein the antigen is selected from a bacteria, a virus and a fungus and the method further comprises administering to the subject G-CSF which increases expression of FcαRI on Kupffer cells and the complex comprising a portion of monomeric IgA that binds to FcαRI, linked to a second portion (i.e., antigen-binding domain) that binds a target cell or antigen is administered by injection.

van Spriel et al teach a method of treating a fungal infection in a subject comprising administering G-CSF followed by injection of a bispecific antibody comprising a FcαRI F(ab) fragment linked to *C. albicans* directed $F(ab')_2$ fragments, which effectively enhanced the killing (i.e., elimination) of *C. albicans* (see entire document, particularly pages 664-665). As evidenced by Van Egmond et al FcαRI are expressed on liver Kupffer cells and receptor expression is induced by G-CSF (see pages 681 and 682, right column). Thus, FcαRI is necessarily present on liver Kupffer cells and the expression of FcαRI is necessarily induced upon administration of G-CSF.

Thus, van Spriel et al anticipate the claims as evidenced by Van Egmond et al.

8. Claims 1 and 6-12 are rejected under 35 U.S.C. 102(e) as being anticipated by Deo et al (US Patent 5,922,845, filed 7/11/1996) as evidenced by Van Egmond et al (Nature Medicine, 6(6):68-685, June 2000, Ids reference F2 filed 1/22/02).

The claims are interpreted as being drawn to a method for eliminating a target cell or antigen from the circulatory system of a subject comprising administering to the subject a complex comprising a portion of monomeric IgA (i.e., $F(ab')_2$ fragment) that binds to FcαRI, linked to a second portion (i.e., antigen-binding domain) that binds a

target cell or antigen wherein the target cell is a cancer cell and the antigen is selected from a bacteria, a virus and a fungus and the method further comprises administering to the subject G-CSF which increases expression of FcαRI on Kupffer cells and the complex comprising a portion of monomeric IgA that binds to FcαRI, linked to a second portion (i.e., antigen-binding domain) that binds a target cell or antigen is administered by intravenous injection.

Doe et al teach a method of eliminating an unwanted cell in a subject comprising administering a mutlispecific molecule comprising an FcαRI specific antigen-binding fragment (i.e., Fab, Fab', $F(ab')_2$, Fv or single-chain Fv) linked to an antibody or antigen-binding fragment thereof that binds a bacteria, virus, fungi or cancer cell, wherein said multispecific molecule is administered by intravenous injection and the method further comprises the administration of G-CSF which enhances the number of Fcα receptors (i.e., FcαRI) (see entire document, particularly column 4, lines 10-26, column 10, column 11, lines 18-36, columns 12-14, column 21, lines 35-43 and Examples). As evidenced by Van Egmond et al FcαRI are expressed on liver Kupffer cells and receptor expression is induced by G-CSF (see pages 681 and 682, right column). Thus, FcαRI is necessarily present on liver Kupffer cells and the expression of FcαRI is necessarily induced upon administration of G-CSF.

Thus, Doe et al anticipate the claims as evidenced by Van Egmond et al.

Conclusion

9. No claim is allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Blanchard whose telephone number is (571) 272-0827. The examiner can normally be reached at Monday through Friday from 8:00 AM to 6:00 PM, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached at (571) 272-0832. The official fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,
David J. Blanchard
571-272-0827

LARRY R. HELMS, PH.D.
SUPERVISORY PATENT EXAMINER

George C. Elliott, Ph.D
Director
Technology Center 1600